UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re: EpiPen ERISA Litigation,

Civ. No. 17-1884 (PAM/HB)

MEMORANDUM AND ORDER

This matter is before the Court on Defendants' Motions to Dismiss. For the following reasons, the Motions are granted in part and denied in part.

BACKGROUND

The individual Plaintiffs in these consolidated putative class actions are participants in health insurance plans that are subject to the requirements of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001 et seq. (Consol. Class Action Compl. (Docket No. 196) ¶¶ 11-29.)¹ They allege that they or their dependents require EpiPens, a prescription medication, to manage serious allergic reactions. (Id.) According to Plaintiffs, in 2007 the list price for a pack of two EpiPens was less than \$100. (Id. ¶ 54.) That year, however, Mylan Pharmaceuticals, Inc. and its related entities, Mylan N.V. and Mylan Specialty L.P., acquired the exclusive rights to market and distribute EpiPens. In the intervening decade, the price for two EpiPens has soared to more than \$600. (Id.) According to Plaintiffs, because of the high deductibles of their health-insurance plans as well as the conduct they complain about in this lawsuit, they are often forced to pay nearly the entire list price for EpiPens. (E.g., id. ¶ 15.)

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¹ The Court will hereafter refer to the Consolidated Class Action Complaint as simply the Complaint.

Defendants CVS Health Corporation, CaremarkPCS Health L.L.C, Caremark L.L.C., Caremark Rx L.L.C. (collectively, "CVS Caremark"), Express Scripts Holding Company, Express Scripts, Inc., Medco Health Solutions, Inc. (collectively, "Express Scripts"), UnitedHealthGroup, Inc., UnitedHealthcare Services, Inc., Optum, Inc., Optum Rx Holdings, LLC, OptumRx, Inc. (collectively, "Optum"), and Prime Therapeutics, LLC are pharmacy benefit managers, or PBMs. PBMs are "middlemen" in the prescription-drug-benefit market. They develop and maintain lists of drugs, known as formularies, from which participants in a health-insurance plan must choose for their pharmaceutical needs. They also negotiate with drug manufacturers and distributors for volume discounts and rebates in exchange for inclusion and preferential placement of the drug on formularies, and exclusion of competitor's drugs from formularies. According to Plaintiffs, Defendants control more than 80% of the prescription-drug-benefit market "and possess the market power of more than 200 million" Americans. (Compl. ¶ 2.)

Plaintiffs allege that Defendants' negotiations with Mylan caused Mylan to raise the price of EpiPens, while Defendants pocketed millions of dollars in rebates and other payments. Because the price Mylan charges for EpiPens directly affects the amount a plan's beneficiaries pay for the EpiPens, Mylan's price increases raised Plaintiffs' out-of-pocket costs dramatically. (Id. ¶ 7.) Plaintiffs assert that Defendants breached their fiduciary duties under ERISA § 404(a), 29 U.S.C. § 1104(a), and engaged in fiduciary self-dealing in violation of ERISA § 406(b), 29 U.S.C. § 1106(b).

Defendants seek dismissal of the Complaint under Rule 12(b)(1), arguing that Plaintiffs cannot establish that their injuries are traceable to Defendants' conduct, nor are

their injuries redressable by the injunctive relief they seek, and thus Plaintiffs lack standing to pursue their claims. In the alternative, Defendants contend that Plaintiffs have failed to state any claims on which relief can be granted under Rule 12(b)(6) because the PBMs are not ERISA fiduciaries.

DISCUSSION

To survive a motion to dismiss under Rule 12(b)(6), a complaint need only "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Fed. R. Civ. P. 12(b)(6). A claim bears facial plausibility when it allows the Court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. When evaluating a motion to dismiss under Rule 12(b)(6), the Court must accept plausible factual allegations as true. Gomez v. Wells Fargo Bank, N.A., 676 F.3d 655, 660 (8th Cir. 2012). But "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are insufficient to support a claim. Iqbal, 556 U.S. at 678.

A. Standing

1. Injury

Plaintiffs claim to have suffered injury in the form of higher copayment and deductible costs for purchasing the EpiPens they require. Defendants contend that this injury is not fairly traceable to the conduct complained of. According to Defendants, the higher price for EpiPens is a function only of Mylan's business decisions. But Plaintiffs have plausibly alleged that Defendants' demands for rebates and other payments caused

Mylan to raise the price of EpiPens. At this preliminary stage of the litigation, that is sufficient.

2. Redressability

Defendants do not take issue with Plaintiffs' standing as to monetary or other equitable relief, contending only that the requested injunctive relief will not redress their injuries. But if the Court were to enter an injunction in Plaintiffs' favor, it is plausible that Mylan would lower the price of EpiPens as a result. Again, at this preliminary stage, Plaintiffs have sufficiently alleged that their injuries would be redressed by an injunction.

Defendants' Motion under 12(b)(1) is denied.

B. Fiduciary Duties

ERISA imposes on all plan fiduciaries the duty of prudence and loyalty. 29 U.S.C. §§ 1104(a)(1)(A), (B). Defendants contend that they are not fiduciaries and that, even if they were, Plaintiffs have failed to plausibly allege that they breached any duties.

A party may become an ERISA fiduciary by being designated as such in the plan documents or if a named fiduciary expressly delegates fiduciary authority to the party pursuant to the plan's terms. <u>Abraha v. Colonial Parking, Inc.</u>, 243 F. Supp. 3d 179, 185 (D.D.C. 2017). There is no dispute that Defendants are not named fiduciaries in any of Plaintiffs' plans, nor have plan fiduciaries specifically delegated fiduciary authority to Defendants.

A party may also become a fiduciary "by exercising de facto control over an area of plan management or administration." <u>Id.</u> "[A] party not specifically named as a fiduciary of a plan owes a fiduciary duty only 'to the extent' that party (i) exercises any discretionary

authority or control over management of the plan or its assets; (ii) offers 'investment advice for a fee' to plan members; or (iii) has 'discretionary authority' over plan 'administration.'"

McCaffree Fin. Corp. v. Principal Life Ins. Co., 811 F.3d 998, 1002 (8th Cir. 2016) (citing 29 U.S.C. § 1002(21)(A) (quotation omitted)). Fiduciary status under ERISA "is not an all-or-nothing concept" id. (quotation omitted), and the relevant question is whether the party "was acting as a fiduciary . . . when taking the action subject to complaint." Pegram v. Herdich, 530 U.S. 211, 226 (2000). In other words, there must be a "'nexus' between the alleged basis for fiduciary responsibility and the wrongdoing alleged in the complaint." McCaffree, 811 F.3d at 1002 (quotation omitted).

1. Discretion

Defendants argue that they are not fiduciaries because the amount of the rebates or other fees that they pay the plans are set by contracts that were negotiated at arm's length. See, e.g., Hecker v. Deere & Co., 556 F.3d 575, 583 (7th Cir. 2009) (noting that "a service provider does not act as a fiduciary with respect to the terms in the service agreement if it does not control the named fiduciary's negotiation and approval of those terms"). But the converse is also true: where the service provider retains the discretion to change the fees it charges, it can be a fiduciary with respect to those fees. See, e.g., F.H. Krear & Co. v. Nineteen Named Trustees, 810 F.2d 1250, 1259 (2d Cir. 1987) ("On the other hand, after a person has entered into an agreement with an ERISA-covered plan, the agreement may

give it such control over factors that determine the actual amount of its compensation that the person thereby becomes an ERISA fiduciary with respect to that compensation.").

Defendants cite to excerpts from their contracts with health insurers or other health benefit plans in arguing that these agreements do not give them discretion to set the fees they charge to the plans. But Plaintiffs dispute this contention, arguing that Defendants could and did change how they characterized drug-manufacturer payments—as rebates, administrative fees, or other types of payments—to allow Defendants to keep more of the money and pay less to the plans. Thus, according to Plaintiffs, Defendants controlled the amount of their compensation.

On a motion to dismiss, the consideration of evidence is not appropriate. Defendants contend that the contracts between them and the plans are necessarily subsumed by the pleadings, but at this preliminary stage, the Court will not construe the complicated and multi-faceted agreements at issue here as a matter of law. See BJC Health Sys. v. Columbia Cas. Co., 348 F.3d 685, 688 (8th Cir. 2003) (finding that contracts submitted with motion to dismiss were outside the pleadings). And given Plaintiffs' allegation that other agreements, such as confidential agreements between Defendants and Mylan and between Defendants and pharmacies, also affected the price they paid for EpiPens, the Court cannot determine that the contracts Defendants provided are sufficient to rebut Plaintiffs' contentions. The cases Defendants cite are not to the contrary. See, e.g., Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 463, 366 (7th Cir. 2007) (considering contracts between plan and PBM that plaintiff attached to its complaint).

Plaintiffs have plausibly alleged that Defendants control the amount they receive in rebates or other fees from Mylan and likewise exercise discretion over how much of that money is paid to the plans. This conduct is different from that at issue in the cases Defendants cite, such as the <u>Carpenters</u> case above. In that case, the plan asserted that the PBM was a fiduciary with regard to the payments specified in the contracts between the plan and the PBM. Here, on the other hand, Plaintiffs assert that the fiduciary relationship stems not from the required contractual payments, but from the PBMs' actions that line its own pockets at the expense of plan participants.

Defendants' reliance on In re UnitedHealth Group PBM Litigation, Civ. No. 16-3352, 2017 WL 6512222 (D. Minn. Dec. 19, 2017) (Ericksen, J.) ("In re UHG"), is similarly misplaced. In In re UHG, the court noted that "[a] person may become a fiduciary with respect to compensation if a plan gives the person control over factors . . . that determine the amount of that person's compensation, as sourced from plan assets." Id. at *9. But plaintiffs in that case did not allege that the PBM defendants had discretion over the amounts at issue. Id. Plaintiffs here have sufficiently alleged that Defendants had discretion to determine the amount of their compensation as sourced from plan assets. Moreover, while "negotiating prices with providers is also not a fiduciary function," id., Plaintiffs here assert that the claimed arms'-length bargaining between Defendants and Mylan was in fact a concerted effort to raise the price for EpiPens, increasing profits for both Defendants and Mylan but injuring Plaintiffs in the process. Cf., e.g., McCaffree, 811 F.3d at 1003 (discussing service provider's assumption of fiduciary duties). Thus, with

respect to EpiPen payments, at least, Plaintiffs have plausibly alleged that Defendants are plan fiduciaries.

2. Breach of fiduciary duties

Plaintiffs have plausibly alleged that Defendants breached their fiduciary duties under section 404(b). Plaintiffs assert that Defendants negotiated such large "rebates" and other payments from Mylan that it caused Plaintiffs' out-of-pocket expenses for EpiPens to increase exponentially. At this stage, that is sufficient to plead a breach.

3. Self-dealing

Plaintiffs also claim that Defendants have violated ERISA's prohibition on fiduciary self-dealing. Plaintiffs claim specifically that Defendants' conduct constitutes (1) dealing with plan assets in Defendants' own interest, 29 U.S.C. § 1106(b)(1); (2) acting on behalf of a party whose interests are adverse either to the plan's interests or to the interests of participants or beneficiaries, id. § 1106(b)(2); and/or (3) receiving money for themselves from a party dealing with the plan "in connection with a transaction involving the assets of the plan." Id. § 1106(b)(3). Defendants argue that Plaintiffs have not plausibly pled a violation of any of these subsections.

Defendants first contend that Plaintiffs have failed to plausibly allege that Defendants acted to benefit themselves as the expense of the plan or plan participants. To support this argument, they point to Plaintiffs' allegation regarding EpiPen's net price, which has remained relatively flat. (Defs.' Supp. Mem. (Docket No. 214) at 49 (citing Compl. ¶ 118).) But Plaintiffs allege that Defendants' rebate and fee deals with Mylan raised the list price of EpiPens, not the net price, and that Plaintiffs' out-of-pocket

expenses, for coinsurance or pre-deductible payments, were tied to the list price, not the net price. (Compl. ¶¶ 125, 132.) Thus, Plaintiffs have sufficiently alleged that Defendants' conduct was at the expense of plan participants and the plans themselves.

Defendants also contend that Plaintiffs' self-dealing claims fail because there are no plan assets involved.² According to Plaintiffs, a plan asset is something that "may be used to the benefit (financial or otherwise) of the fiduciary at the expense of plan participants or beneficiaries." Acosta v Pac. Enters., 950 F.2d 611, 620 (9th Cir. 1991). Thus, Plaintiffs argue, Defendants use their pre-existing contracts with health plans—and the consequent access to large pools of pharmaceutical-purchasing consumers—as leverage to extract greater rebates and fees from drug manufacturers, thereby increasing the cost of such drugs for the consumers.

But rather than argue explicitly that Defendants' market power is a plan asset, Plaintiffs instead claim that the administrative services agreements between the plans and insurers, or the contracts between plans and PBMs, constitute plan assets. Alternatively, they contend that the drug formularies are plan assets, or that the excess amounts that the plans or Plaintiffs must pay for EpiPens as a result of Defendants' negotiated rebates and fees are plan assets.

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² The involvement of plan assets is relevant both for Plaintiffs' self-dealing claims and Plaintiffs' alternative argument that Defendants are plan fiduciaries because Defendants "exercise[d] any authority or control respecting management or disposition of [a plan's] assets" under § 1002(21)(A)(i), which imposes fiduciary responsibilities without regard to a party's discretionary authority or control. Having determined that Plaintiffs plausibly alleged Defendants' fiduciary status with respect to plan administration, the Court need not determine whether Defendants exercised control of the management or disposition of plan assets.

Although ERISA does not define what constitutes plan assets, "[t]he Secretary of Labor has repeatedly defined 'plan assets' consistently with 'ordinary notions of property rights.'" Kalda v. Sioux Valley Physician Partners, Inc., 481 F.3d 639, 647 (8th Cir. 2007) (quotation omitted). "Plan assets include cash, financial instruments, and other property that may be used to the benefit of the fiduciary at the expense of plan participants." In re UHG, 2017 WL 6512222, at *10. "If a plan does not have a right to certain property, then the property is not a plan asset such that fiduciary duties apply to the disposition of that property." Id. Under this definition, Defendants' formularies, which are Defendants' proprietary information, are not "property" of the plan. Nor are Plaintiffs' or the plans' excess payments for EpiPens plan assets. See id. (finding that participants' out-of-pocket expenses are not plan assets).

The agreements between Defendants and Mylan are not plan assets—the plans have no property rights in agreements to which they are not parties. Nor are the administrative services agreements between plans and insurers plan assets for purposes of any fiduciary duty on the part of Defendants, because Defendants are not parties to these agreements. The only possible plan assets involved here are the contracts between Defendants and the plans themselves.

But the conduct Plaintiffs allege here is extra-contractual—it is conduct that is contrary to either the letter or spirit of the contracts between Defendants and the plans. For example, Plaintiffs assert that, although Defendants are contractually required to remit the "rebates" they receive from Mylan to the plans, Defendants characterize payments from Mylan as "fees" or other types of payments, thereby avoiding the contractual requirements.

This conduct, while plausibly a breach of § 1104, as discussed above, does not involve plan

assets or transactions for purposes of ERISA's self-dealing prohibitions. Plaintiffs' claims

under § 1106 therefore fail.

CONCLUSION

Plaintiffs have plausibly alleged that they suffered an injury that is redressable by

the relief they seek. They have also plausibly pleaded their fiduciary-duty claim under

ERISA § 404 but have not done so under § 406. Accordingly, IT IS HEREBY

ORDERED that:

1. CVS Caremark's Motion to Dismiss (Docket No. 209) is **GRANTED in**

part and **DENIED** in part;

2. Express Script's Motion to Dismiss (Docket No. 210) is **GRANTED in part**

and **DENIED** in part;

3. Optum's Motion to Dismiss (Docket No. 211) is **GRANTED in part** and

DENIED in part; and

4. Prime Therapeutics's Motion to Dismiss (Docket No. 212) is **GRANTED in**

part and **DENIED** in part.

Dated: October 26, 2018

s/Paul A. Magnuson

Paul A. Magnuson

United States District Court Judge

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